

TENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 02PP174	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2002/001875	International filing date (day/month/year) 08 OCTOBER 2002 (08.10.2002)	Priority date (day/month/year) 14 AUGUST 2002 (14.08.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 31/164		
Applicant KIM, Tae-Yoon et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	<p>This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
3.	<p>This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 24 MARCH 2004 (24.03.2004)	Date of completion of this report 03 DECEMBER 2004 (03.12.2004)
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International application No.

PCT/KR2002/001875

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-19	YES
	Claims		NO
Inventive step (IS)	Claims	1-19	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	15-19	NO

2. Citations and explanations (Rule 70.7)

The following documents have been considered for the purpose of this report:

D1 : FEBS LETTERS, 2001, vol.499, pp.82-6

D2 : Journal of Neurochemistry, 2000, vol.75, no.3, pp.1053-9

(not cited in the search report)

D3 : Cellular and molecular biology, 2000, vol.46, no.1, pp.111-9

(not cited in the search report)

The present invention relates to compositions containing phytosphingosine derivatives for the induction of apoptosis.

D1 discloses that phytosphingosine and N-acetyl phytosphingosine inhibit carbachol-induced activation of phospholipase D in CHO cells and exert strong cytotoxic effects on CHO cells.

D2 suggests that phospholipase D2 activity has a suppressive role in H₂O₂-induced apoptosis in rat pheochromocytoma cells.

D3 discloses that vitamin D₃ and calcipotriol induce apoptosis in the keratinocyte cell.

1. Novelty

None of the prior art discloses that phytosphingosine derivatives induce apoptosis. Therefore, the present invention is novel.

(Continued on Supplemental Sheet.)

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The term "CLA-phytosphingosine(CLA-PS)" used in the detailed description and claim 2 is vague and unclear because its structure is not described or "CLA" is not well-recognized expression.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

2. Inventive Step

From the disclosure of D1 and D2 that phytosphingosine derivatives inhibit phospholipase D which has a suppressive role in apoptosis, it is obvious at a glance that phytosphingosine derivatives finally induce apoptosis. However, according to D2 phospholipase D activity is increased during Jurkat T cell apoptosis, and the author of D2 concludes that nothing has been known about the definite role of the phospholipase D activity in apoptosis process. Therefore, the skilled person would not have found an incentive to combine D1 and D2 to arrive at the present invention.

As a consequence, the present invention is considered to involve an inventive step.

3. Industrial applicability

For the assessment of the presently worded claims 15 to 19 on the question whether their subject-matter is industrially applicable, no unified criteria exist in the PCT. The patentability under national patent laws can also be dependent on the formulation of the claims. The KIPO, for example, does not recognize the subject-matter of claims to the method of treatment as being industrially applicable.